

REMARKS

Claims 35, 37, 53 and 54 are pending in the instant application after entry of the instant Response. Claims 35, 37, 53 and 54 are amended and Claims 1-34, 39-50, and 52 are canceled by the instant Response. Support for these amendments is present throughout the application as filed, and no new matter is introduced by way of the above-described amendments to the claims.

I. Claim Rejection: 35 U.S.C. § 102

Claims 35, 37, 50, 53, and 54 stand rejected under 35 U.S.C. § 102, as anticipated by Bartholomeusz et al., (WO 2003/066841). Specifically, the Examiner argues that Bartholomeusz et al. discloses particular mutations (rL180M and sI195M) that fall within the scope of the instant claims. For the reasons outlined below, Applicants respectfully traverse this rejection.

As a preliminary matter, Applicants note that Claim 50 has been canceled without prejudice to the pursuit of that subject matter in one or more related applications. Accordingly, Applicants respectfully submit that the rejection of that claim has been rendered moot. Furthermore, Applicants respectfully submit that, without acquiescing in the propriety of this rejection, the pending claims are directed to a methods wherein a specific mutations is employed to discern whether a HBV variant will exhibit reduced sensitivity to a nucleoside or nucleotide analog. As Bartholomeusz et al. does not teach the presently claimed mutations, the cited reference is insufficient to anticipate the pending claims. Accordingly, Applicants respectfully request withdrawal of the instant rejection.

II. *Claim Rejection: Obviousness-Type Double Patenting*

Claims 35, 37, 50, 53, and 54 stand provisionally rejected on the grounds of non-statutory obviousness type double patenting over certain claims of one issued patent and four pending applications. To facilitate Applicants' response to this provisional rejection, the issued patent and four pending applications and the cited claims of each are detailed in the following table.

USSN	Cited Claims	Claimed Subject Matter
6,555,311	Claims 11-18	The cited claims do not recite the claimed mutations
11/913,106	Claims 34-60	The cited claims do not recite the claimed mutations
11/932,410	Claims 10-18, 25-56, 79-80, 87- 88, and 90	The cited claims are either canceled or do not recite the claimed mutations
12/346,622	Claims 1-77	The cited claims are either canceled or do not recite the claimed mutations
12/384,132	Claims 1-13	The cited claims do not recite the claimed mutations

As noted by the Examiner, a nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one of the claims pending in an application is not patentably distinct from one or more reference claims because the pending application claim is either anticipated by, or would have been obvious over, the reference claims. (See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); and *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985)). As the table, above, indicates, none of the cited claims teach the claimed combination and thus the cited art cannot anticipate the pending claims. Therefore, the analysis to be employed in the reviewing the instant obviousness-type double patenting rejections parallels the guidelines for analysis of a 35 U.S.C. § 103 obviousness determination.

(See *In re Braat*, 937 F.2d 589, 19 USPQ2d 1289 (Fed. Cir. 1991); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985)). As detailed below, such a determination of obviousness cannot be established and the provisional rejections should be withdrawn.

As the analysis employed in an obviousness-type double patenting determination parallels the guidelines for a 35 U.S.C. § 103(a) rejection, the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), which form the framework for establishing obviousness under 35 U.S.C. § 103, are employed when undertaking an obvious-type double patenting analysis. These factual inquiries are summarized as follows:

- (A) Determine the scope and content of a patent claim relative to a claim in the application at issue;
- (B) Determine the differences between the scope and content of the patent claim as determined in (A) and the claim in the application at issue;
- (C) Determine the level of ordinary skill in the pertinent art; and
- (D) Evaluate any objective indicia of nonobviousness.

With regard to step (A), Applicants note that the claims of the issued patent and four pending applications recite methods of determining whether a test virus would exhibit reduced sensitivity to nucleoside or nucleotide analogs. However, none of the claims of the cited art specifically recite the mutations being claimed in the instant application. Thus, an appropriate determination of step (B) would highlight the distinct nature of the mutations being assayed in the claim sets. Applicants note that the Examiner has provided no basis as to why one of skill in the art, regardless of what that skill level is, would have had an expectation that the instantly claimed mutations would function in the same manner as those recited in the cited claims of the cited art. Accordingly, Applicants respectfully submit that the pending claims are

not rendered obvious by the cited claims of the cited art. Accordingly, Applicants request withdrawal of the instant rejections.

CONCLUSION

Entry of the foregoing amendments and remarks into the file of the above-identified application is respectfully requested. Applicants respectfully request that all rejections be withdrawn, and that all of the pending claims be allowed.

Respectfully submitted,



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